DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 1, 2015

Fresenius Medical Care
Denise Oppermann
Senior Director, Regulatory Affairs, Devices
920 Winter Street
Waltham, MA 02451

Re: K141997
Trade/Device Name: Crit-Line IV System
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KOC
Dated: March 12, 2015
Received: March 13, 2015

Dear Denise Oppermann,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141997

Device Name
Crit-Line IV System

Indications for Use *(Describe)*

The Crit-Line IV System is used to non-invasively to measure hematocrit, oxygen saturation and percent change in blood volume. The Crit-Line Clip (CLiC) measures hematocrit, percent change in blood volume and oxygen saturation in real time for application in the treatment of dialysis patients with the intended purpose of providing a more effective treatment for both the dialysis patient and the dialysis technician. Based on the data that the monitor provides, the clinician/nurse, under physician direction, intervenes (i.e. increases or decreases the rate at which fluid is removed from the blood) in order to remove the maximum amount of fluid from the dialysis patient without the patient experiencing the common symptoms of dialysis which include nausea, cramping and vomiting.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(K) SUMMARY

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92.

5.1. Submitter's Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC (FMC-RTG)
Address:	920 Winter Street Waltham, MA 02451-1457
Phone:	(781) 699-4479
Fax:	(781) 699-9635
Contact Person:	Denise Oppermann, Senior Director, Regulatory Affairs – Devices
Date of Preparation:	07-22-2014

5.2. Device Name

Trade Name:	Crit-Line IV System
Common Name:	Accessories, blood circuit, hemodialysis
Classification Name:	Hemodialysis system and accessories
Regulatory Class:	Class II per 21 CFR §876.5820
Product Code/Classification Panel:	KOC/ Gastroenterology – Urology

5.3. Legally Marketed Predicate Device

Crit-Line Clip Monitor (CLiC), K121599

Crit-Line III Monitor, K972470

2008T Hemodialysis Machine with optional Crit-Line Clip Monitor (CLiC), K131908

5.4. Device Description

The intended use of the Crit-Line IV System is as a continuous real-time blood monitoring system for displaying information measured by the CLiC sensor, including hematocrit, oxygen saturation, and percent change in blood volume. The Crit-Line IV System is comprised of the Crit-Line IV monitor (the subject of this submission), the Crit-Line Clip (CLiC) sensor, and the Crit-Line Clip Blood Chamber. The touchscreen interface and display of the Crit-Line IV monitor is used with the hardware and software of the CLiC sensor, which is a separate component of the Crit-Line Clip (CLiC) Monitor, K121599. Information displayed on the Crit-Line IV monitor may be viewed real-time during a dialysis treatment. There are additional display features incorporated into the Crit-Line IV System, which are similar to that of the Crit-Line III system (K972470) and the 2008T Hemodialysis Machine with (optional) CLiC (K131908). For this reason, the Crit-Line Clip Monitor (CLiC: K121599), is the predominant predicate and the 2008T Hemodialysis Machine with (optional) CLiC (K131908) and the Crit-Line III (K972470) are reference predicate devices.

5.5. Indications for Use

The Crit Line IV System is used to non-invasively measure hematocrit, oxygen saturation and percent change in blood volume. The Crit-Line Clip (CLiC) measures hematocrit, percent change in blood volume and oxygen saturation in real time for application in the treatment of dialysis patients with the intended purpose of providing a more effective treatment for both the dialysis patient and the clinician. Based on the data that the monitor provides, the clinician/nurse, under physician direction, intervenes (i.e. increases or decreases the rate at which fluid is removed from the blood) in order to remove the maximum amount of fluid from the dialysis patient without the patient experiencing the common complications of dialysis which include nausea, cramping and vomiting.

5.6. Intended Use

The intended use of the Crit-Line IV System is as a continuous real-time monitor of hematocrit, oxygen saturation, and percent change in blood volume.

5.7. Technological Characteristics

Fundamental Scientific Technology/Operating Principle:

The Crit-Line IV System consists of a monitor running display software for data measured by the CLiC sensor. The data is sent as USB serial signals from the CLiC sensor to the monitor. The Crit-Line IV monitor connects with the CLiC sensor via the USB computer interface. The CLiC sensor connects to the external transparent section of a single-use Crit-Line Clip Blood Chamber. The Crit-Line Clip Blood Chamber provides in-line optic measurement access (non-invasive) to blood via connection to the dialysis tubing set.

The Crit-Line IV monitor displays and stores data generated by the CLiC sensor.

- The Crit-Line IV monitor is a dedicated compact display unit which can be

mounted to an IV pole. The monitor continuously displays volume (ΔBV%), hematocrit (Hct), estimated hemoglobin (Hb, Hct based estimate), and oxygen saturation (O2 Sat).

- A ZigBee wireless module allows the user to wirelessly print or download data collected during the monitoring session.

The display software of the Crit-Line monitor provides the following user interfaces:

- Touch screen. Virtual buttons on the screen allow the user to navigate through the menu selections. The screen also allows for data entry, such as user ID, and for language selection.
- File System. Data collected during the monitoring sessions will be maintained for a period of 30 days. Data stored in the patient run files are available for transfer to host computer systems or to a USB memory stick.

The above bulleted items represent the main differences between the function of the display software described in K121599 and K131908 as compared with the proposed monitor software of the Crit-Line IV System. Additional alerts, such as a "ΔBV% greater than 8%/hr" alert, were added to enhance the user interface. The intended use and use environment are the same as that of the predicate monitoring devices. The algorithms used in the proposed monitor software for calculating ΔBV% and estimating hemoglobin (Hb) are the same algorithms used in the software driver provided with the predicate Crit-Line Clip (CLiC), K121599.

5.8. Performance Data

Performance testing requirements were determined through the application of a risk management process and applicable performance standards. Performance testing included software verification, electrical safety testing, electromagnetic compatibility (EMC) testing, intentional EM emissions immunity simulation testing, coexistence testing with RFID equipment, ship testing, and usability testing.

5.9. Conclusion

The information provided in this submission demonstrates the Crit-Line IV System functions as intended and is substantially equivalent to the predicate devices. The test results demonstrate that the proposed device does not raise any new concerns with regard to safety or effectiveness.